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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MACAULEY, SHERIDAN R

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

10/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,121	Applicant(s) BLUME ET AL.	
	Examiner SHERIDAN R. MACAULEY	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-23 is/are pending in the application.
- 4a) Of the above claim(s) 3,9,10,15,19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-8,11-14,16-18 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/28/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-3 and 6-23 are pending.

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-18 and 21-23) and a preparation comprising a microcirculation-promoting substance and a vasoprotective agent as the species of preparation, aescin as the species of vasoprotective agents and caffeine as the species of microcirculation-promoting agent in the reply filed on July 27, 2009 is acknowledged. The traversal is on the ground(s) that the technical feature that is common to the groups was not known in the art at the time of the invention. This is not found persuasive because the technical feature that is common to the groups is a preparation having a carrier system comprising membrane-forming lipids, a microcirculation-promoting substance and an anticoagulant or vasoprotective agent. Cho et al. (US 5,667,793) teach the claimed preparation, such as that of Example 5 (see column 9), which teaches a composition comprising a carrier system comprising membrane-forming lipids (ceramide lipids), a microcirculation-promoting substance (caffeine) and a vasoprotective agent (escin, i.e., aescin). Therefore, there is no special technical feature that is common to the groups or species of the invention that makes a contribution over the prior art. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 3, 9, 10, 15, 19 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions and species, there being no allowable generic or linking claim.
3. Claims 1, 2, 6-8, 11-14, 16-18 and 21-23 are examined on the merits in this office action.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 6, 7, 11-14, 18, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Cho et al. (US 5,667,793). The claims recite a combined cosmetic or therapeutic composition having a carrier system comprising membrane forming lipids and at least one microcirculation-promoting substance, specifically caffeine, and at least one active ingredient which is a vasoprotective agent, specifically aescin. The claims further recite that the carrier system is vesicular and that the membrane-forming lipids include phospholipids, ceramides and diacylglycosides. The claims further recite that the vasoprotective agent is in an amount of 0.1-7% by weight and the microcirculation-promoting substance is present at 0.1-2% by weight. The claims further recite that the preparation contains 10-25% ethanol.

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6. Cho teaches a therapeutic composition comprising a carrier system comprising membrane-forming lipids (ceramide lipids), a microcirculation-promoting substance (caffeine) and a vasoprotective agent (0.5% escin, i.e., aescin; see Example 5, column 9). The reference teaches that caffeine may be present at 0.5-3% by weight (col. 3, lines 49-59). Cho teaches that the compositions may comprise ethanol at 25% (see Example 7, column 10).

7. Therefore, the reference anticipates all of the limitations of the cited claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1, 2, 6-8, 11-14, 16-18 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al. (US 5,667,793) in view of Bombardelli et al. (US 5,679,358). The claims recite a combined cosmetic or therapeutic composition having a

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carrier system comprising membrane forming lipids and at least one microcirculation-promoting substance, specifically caffeine, and at least one active ingredient which is a vasoprotective agent, specifically aescin. The claims further recite that the carrier system is vesicular and that the membrane-forming lipids include phospholipids, ceramides and diacylglycosides. The claims further recite that the vasoprotective agent is in an amount of 0.1-7% by weight, specifically 4-6% aescin, and the microcirculation-promoting substance is present at 0.1-2% by weight, specifically 0.5-1.5% caffeine. The claims further recite that the membrane forming lipids contain at least 70% by weight phosphatidylcholine and that the carrier system contains linoleic acid in stabilized form in an amount of 2.5-4.5% by weight. The claims also recite that the preparation further contains at least one thermoreceptor-agonist selected from capsaicin in an amount of 0.1-1% by weight and nicotinic acid, nicotinic acid amide, nicotinic acid ester or mixtures thereof in an amount of 0.5-5% by weight. The claims further recite that the preparation contains 10-25% ethanol.

11. Cho teaches a therapeutic compositions for the treatment of cellulite comprising a carrier system comprising membrane-forming lipids (ceramide lipids), a microcirculation-promoting substance (caffeine) and a vasoprotective agent (0.5% aescin, i.e., aescin; see Example 5, column 9). The reference teaches that caffeine may be present at 0.5-3% by weight (col. 3, lines 49-59). Cho teaches that the compositions may comprise ethanol at 25% (see Example 7, column 10). Cho teaches that the composition may comprise trilinoleate (a stabilized linoleic acid; col. 5, lines 4-14) and nicotinate (nicotinic acid; col. 4, lines 38-40). Cho does not specifically teach a

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composition comprising phosphatidylcholine or that the composition comprises lineolic acid, nicotinic acid or aescin in the amounts recited in the claims.

12. Bombardelli teaches compositions for the treatment of cellulite comprising agents to improve circulation such as caffeine and phosphotidylcholine as a membrane forming lipid (abstract, col. 4-5, Example II).

13. At the time of the invention, a composition comprising nearly all of the claimed components was known in the art, as taught by Cho. It was further known that similar compositions for the same purpose, the treatment of cellulite, could have been formulated with phosphotidylcholine as the membrane-forming lipid, as taught by Bombardelli. One of ordinary skill in the art would have been motivated to combine these teachings with a reasonable expectation of success by using phosphotidylcholine in the method of Cho because Cho teaches that any known carrier for similar preparations would have been useful as the carrier in the composition, and Bombardelli teaches that such preparations comprising phosphatidylcholine are favorable. Further, Cho teaches that the emollient, such as the lineolic acid, may be present in amounts between about 5% and 30% (col. 4, lines 64-67, col. 5, lines 4-14). One of ordinary skill in the art would therefore have been motivated to use lineolic acid in the composition at 4.5% in the course of routine optimization of the composition. Also, although the reference does not specifically teach the amount of nicotinic acid or aescin recited in the claims, the additional components taught by the reference that may be included in the compositions are present at amounts within those ranges and one of ordinary skill in the art would have been motivated to add the additional components in amounts within the

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claimed ranges. It would therefore have been obvious to one of ordinary skill in the art to combine the cited teachings of the prior art to arrive at the claimed invention.

14. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A. Davis/

Primary Examiner, Art Unit 1651